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ThermoQuest

SECTION 10

510(k) SUMMARY

Submitted By: Richard L. Miller
Manager – Regulatory Compliance
Forma Scientific, Inc.
Mill Creek Road
Marietta, Ohio 45750

May 11, 2000

Names of Devices:

Trade Name:	Forma Scientific Incubator
Common/Usual Name:	Embryo Incubator
Classification Name:	Embryo Incubator 21 CFR 884.6120

Predicate Device: 63 FR 48428, September 10, 1998

Device Description:
The Forma Scientific incubators are bench top, or floor standing units. They control carbon dioxide (CO_2), temperature and provide elevated humidity. Controlled parameters and alarm functions are microprocessor controlled. The volume of each chamber is approximately 6.5 cubic feet (184 liters).

Intended Use:
The Forma Scientific Direct Heat Incubators are intended to be used to store and preserve gametes and/or embryos at or near body temperature.

Substantial Equivalence:
In accordance with the Final Rule on reclassification of Medical Devices Used for In Vitro Fertilization, Forma Scientific cites the Final Rule as support for substantial equivalence.

Discussion of Tests and Test Results:
The Forma Scientific Direct Heat Incubators were subjected to electrical safety, electromagnetic compatibility acceptability and operating performance. The incubators passed all these tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2000

Mr. Richard L. Miller
Manager of Regulatory Compliance
ThermoQuest Corporation
Forma Scientific Division
Mill Creek Road
Marietta, OH 45750

Re: K001524
Forma Scientific Direct Heat Incubator
Dated: May 11, 2000
Received: May 16, 2000
Regulatory Class: II
21 CFR §884.6120/Procode: 85 MQG

Dear Mr. Miller:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K001524

Device Name: **Embryo Incubator**

Indications For Use:

The intended use of these incubators is to provide an environment with controlled temperature, CO_2 and an elevated humidity, for the development of ova or embryos.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001524